



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-9126-N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances— July through September 2020

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice

SUMMARY: This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published from July through September 2020, relating to the Medicare and Medicaid programs and other programs administered by CMS.

FOR FURTHER INFORMATION CONTACT: It is possible that an interested party may need specific information and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing contact persons to answer general questions concerning each of the addenda published in this notice.

Addenda	Contact	Phone Number
I CMS Manual Instructions	Ismael Torres	(410) 786-1864
II Regulation Documents Published in the Federal Register	Terri Plumb	(410) 786-4481
III CMS Rulings	Tiffany Lafferty	(410) 786-7548
IV Medicare National Coverage Determinations	Wanda Belle, MPA	(410) 786-7491
V FDA-Approved Category B IDEs	John Manlove	(410) 786-6877
VI Collections of Information	William Parham	(410) 786-4669
VII Medicare –Approved Carotid Stent Facilities	Sarah Fulton, MHS	(410) 786-2749
VIII American College of Cardiology-National Cardiovascular Data Registry Sites	Sarah Fulton, MHS	(410) 786-2749
IX Medicare’s Active Coverage-Related Guidance Documents	JoAnna Baldwin, MS	(410) 786-7205
X One-time Notices Regarding National Coverage Provisions	JoAnna Baldwin, MS	(410) 786-7205
XI National Oncologic Positron Emission Tomography Registry Sites	David Dolan, MBA	(410) 786-3365
XII Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities	David Dolan, MBA	(410) 786-3365
XIII Medicare-Approved Lung Volume Reduction Surgery Facilities	Sarah Fulton, MHS	(410) 786-2749
XIV Medicare-Approved Bariatric Surgery Facilities	Sarah Fulton, MHS	(410) 786-2749
XV Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials	David Dolan, MBA	(410) 786-3365
All Other Information	Annette Brewer	(410) 786-6580

SUPPLEMENTARY INFORMATION:

I. Background

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs and coordination and oversight of private health insurance.

Administration and oversight of these programs involves the following: (1) furnishing information

to Medicare and Medicaid beneficiaries, health care providers, and the public; and (2) maintaining effective communications with CMS regional offices, state governments, state Medicaid agencies, state survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, National Association of Insurance Commissioners (NAIC), health insurers, and other stakeholders. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act) and Public Health Service Act. We also issue various manuals, memoranda, and statements necessary to administer and oversee the programs efficiently.

Section 1871(c) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every 3 months in the **Federal Register**.

II. Format for the Quarterly Issuance Notices

This quarterly notice provides only the specific updates that have occurred in the 3-month period along with a hyperlink to the full listing that is available on the CMS website or the appropriate data registries that are used as our resources. This is the most current up-to-date information and will be available earlier than we publish our quarterly notice. We believe the website list provides more timely access for beneficiaries, providers, and suppliers. We also believe the website offers a more convenient tool for the public to find the full list of qualified providers for these specific services and offers more flexibility and “real time” accessibility. In addition, many of the websites have listservs; that is, the public can subscribe and receive immediate notification of any updates to the website. These listservs avoid the need to check the website, as notification of updates is automatic and sent to the subscriber as they occur. If assessing a website proves to be difficult, the contact person listed can provide information.

III. How to Use the Notice

This notice is organized into 15 addenda so that a reader may access the subjects published during the quarter covered by the notice to determine whether any are of particular interest. We expect this notice to be used in concert with previously published notices. Those unfamiliar with a description of our Medicare manuals should view the manuals at <http://www.cms.gov/manuals>.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Seema Verma, having reviewed and approved this document, authorizes Trenesha Fultz-Mimms, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: October 21, 2020.

Trenesha Fultz-Mimms,

Federal Register Liaison,

Department of Health and Human Services.

Publication Dates for the Previous Four Quarterly Notices

We publish this notice at the end of each quarter reflecting information released by CMS during the previous quarter. The publication dates of the previous four Quarterly Listing of Program Issuances notices are: November 6, 2019 (84 FR 59815), February 13, 2020 (85 FR 8282), April 24, 2020 (85 FR 23030) and August 12, 2020 (85 FR 48691). We are providing only the specific updates that have occurred in the 3-month period along with a hyperlink to the website to access this information and a contact person for questions or additional information.

Addendum I: Medicare and Medicaid Manual Instructions (July through September 2020)

The CMS Manual System is used by CMS program components, partners, providers, contractors, Medicare Advantage organizations, and State Survey Agencies to administer CMS programs. It offers day-to-day operating instructions, policies, and procedures based on statutes and regulations, guidelines, models, and directives. In 2003, we transformed the CMS Program Manuals into a web user-friendly presentation and renamed it the CMS Online Manual System.

How to Obtain Manuals

The Internet-only Manuals (IOMs) are a replica of the Agency's official record copy. Paper-based manuals are CMS manuals that were officially released in hardcopy. The majority of these manuals were transferred into the Internet-only manual (IOM) or retired. Pub 15-1, Pub 15-2 and Pub 45 are exceptions to this rule and are still active paper-based manuals. The remaining paper-based manuals are for reference purposes only. If you notice policy contained in the paper-based manuals that was not transferred to the IOM, send a message via the CMS Feedback tool.

Those wishing to subscribe to old versions of CMS manuals should contact the National Technical Information Service, Department of Commerce, 5301 Shawnee Road, Alexandria, VA 22312 Telephone (703-605-6050). You can download copies of the listed material free of charge at: <http://cms.gov/manuals>.

How to Review Transmittals or Program Memoranda

Those wishing to review transmittals and program memoranda can access this information at a local Federal Depository Library (FDL). Under the FDL program, government publications are sent to approximately 1,400 designated libraries throughout the United States. Some FDLs may have

arrangements to transfer material to a local library not designated as an FDL. Contact any library to locate the nearest FDL. This information is available at <http://www.gpo.gov/libraries/>

In addition, individuals may contact regional depository libraries that receive and retain at least one copy of most federal government publications, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library. CMS publication and transmittal numbers are shown in the listing entitled Medicare and Medicaid Manual Instructions. To help FDLs locate the materials, use the CMS publication and transmittal numbers. For example, to find the manual for National Coverage Determination (NCD30.3.3): Acupuncture for Chronic Low Back Pain (cLBP), use (CMS-Pub. 100-03) Transmittal No. 10337.

Addendum I lists a unique CMS transmittal number for each instruction in our manuals or program memoranda and its subject number. A transmittal may consist of a single or multiple instruction(s). Often, it is necessary to use information in a transmittal in conjunction with information currently in the manual.

Fee-For Service Transmittal Numbers

Please Note: Beginning Friday, March 20, 2020, there will be the following change regarding the Advance Notice of Instructions due to a CMS internal process change. Fee-For Service Transmittal Numbers will no longer be determined by Publication. The Transmittal numbers will be issued by a single numerical sequence beginning with Transmittal Number 10000.

For the purposes of this quarterly notice, we list only the specific updates to the list of manual instructions that have occurred in the 3-month period. This information is available on our website at www.cms.gov/Manuals.

Transmittal Number	Manual/Subject/Publication Number
Medicare General Information (CMS-Pub. 100-01)	
10299	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction

Medicare Benefit Policy (CMS-Pub. 100-02)	
10269	Billing for Home Infusion Therapy Services On or After January 1, 2021 Home Infusion Therapy Services General Requirements for Payment of Home Infusion Therapy Services Home Infusion Therapy Services Benefit is Separate from DME Benefit Qualified Home Infusion Therapy Suppliers Patient Eligibility for Home Infusion Therapy 320.4.1/Home Infusion Therapy Services for Homebound Patients Plan of Care Requirements Notification of Available Infusion Therapy Options Plan of Care Periodic Review and Provider Coordination Professional Services, Including Nursing Services, for Home Infusion Therapy Home Infusion Therapy Services Training and Education Remote Monitoring and Monitoring Services Home Infusion Therapy Drugs Determining Qualifying Home Infusion Drugs Payment for Home Infusion Therapy Services Home Infusion Drug Payment Categories Infusion Drug Administration Calendar Day and Unit of Single Payment 320.8.3/Initial Visits and Subsequent Visits for Home Infusion Therapy Services Medical Review
Medicare National Coverage Determination (CMS-Pub. 100-03)	
10337	National Coverage Determination (NCD30.3.3): Acupuncture for Chronic Low Back Pain (cLBP)
Medicare Claims Processing (CMS-Pub. 100-04)	
10201	October 2020 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files
10202	Medicare Part A Skilled Nursing Facility (SNF) Prospective Payment System (PPS) Pricer Update FY 2021
10207	July 2020 Update of the Hospital Outpatient Prospective Payment System (OPPS)
10210	Update to the Internet Only Manual (IOM) Publication (Pub.) 100-04, Chapter 3, Section 20 and 90.6 Payment Under Prospective Payment System (PPS) Diagnosis Related Groups (DRGs) Intestinal and Multi-Visceral Transplants
10211	Manual Update to Section 20.7 in Chapter 23 of Publication (Pub) 100-04
10213	Influenza Vaccine Payment Allowances - Annual Update for 2020-2021 Season
10214	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
10215	Changes to the Laboratory National Coverage Determination (NCD) Edit Software for October 2020
10216	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
10217	Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
10218	Change to the Payment of Allogeneic Stem Cell Acquisition Services

10221	File Conversions Related to the Spanish Translation of the Healthcare Common Procedure Coding System (HCPCS) Descriptions
10222	Updates in the Fiscal Intermediary Shared System (FISS) Inpatient Provider Specific Files (PSF)
10224	July 2020 Update of the Hospital Outpatient Prospective Payment System (OPPS)
10225	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10229	Modify Edits in the Fee for Service (FFS) System When a Beneficiary has a Medicare Advantage (MA) Plan
10230	New Waived Tests
10232	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
10233	Update to the (IOM) Publication 100-04, Medicare Claims Processing Manual, Chapter 23 – Fee Schedule Administration and Coding Requirements, Section 20.9 - Fee Schedule Administration and Coding Requirements National Correct Coding Initiative (NCCI) Correct Coding Modifier Indicators and HCPCS Codes Modifiers Instructions for Codes with Modifiers (A/B MACs (B) Only) Appeals Procedure-to-Procedure Edits Medically Unlikely Edits Correct Coding Edit (CCE) File Record Format
10236	Update to the IOM Publication (Pub) 100-04, Medicare Claims Processing Manual, Chapters 1, 6, 8, 17, 20, 22, 24, and 31 Referencing the Active Universal Resource Locators (URLs) for the Washington Publishing Company (WPC) and the ASC X12 Organizations, and Updates to the HIPAA Eligibility Transaction System (HETS)
10242	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10244	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10246	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10247	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10249	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10251	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10253	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10254	Penalty for Delayed Request for Anticipated Payment (RAP) Submission – Implementation Addendum A Split Percentage Payment Grouper Links Assessment and Payment Request for Anticipated Payment (RAP) Request for Anticipated Payment (RAP) HH PPS Claims

	Input/Output Record Layout Decision Logic Used by the Pricer on RAPs Decision Logic Used by the Pricer on Claims
10255	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10256	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10257	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10259	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10263	Influenza Vaccine Payment Allowances - Annual Update for 2020-2021 Season
10264	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10265	Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
10266	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10267	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
10269	Billing for Home Infusion Therapy Services On or After January 1, 2021 Home Infusion Therapy Services Policy Coverage Requirements Home Infusion Drugs: Healthcare Common Procedural Coding System (HCPCS) Drug Codes Billing and Payment Requirements Claim Adjustment Reason Codes, Remittance Advice Remark Codes, Group Codes, and Medicare Summary Notice Messages CWF and MCS Editing Requirements
10270	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10272	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10273	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10274	Update to Osteoporosis Drug Codes Billable on Home Health Claims Osteoporosis Injections as HHA Benefit
10276	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10277	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10284	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10285	Instructions for Retrieving the January 2021 Opioid Treatment Program (OTP) Payment Rates Through the CMS Mainframe Telecommunications System
10288	Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - October 2020 Update

10290	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10293	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10296	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10297	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10298	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10305	Changes to the Laboratory National Coverage Determination (NCD) Edit Software for October 2020
10306	October 2020 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files
10312	Inpatient Psychiatric Facilities Prospective Payment System (IPF PPS) Updates for Fiscal Year (FY) 2021
10313	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10314	Medicare Part A Skilled Nursing Facility (SNF) Prospective Payment System (PPS) Pricer Update FY 2021
10318	Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
10319	Removal of Contractor Requirement to Submit Electronic Data Interchange (EDI) Data into the Contractor Reporting of Operational and Workload Data (CROWD) System (Form 5)
10320	Updates to Chapter 23 - Fee Schedule Administration and Coding Requirements Description of Healthcare Common Procedure Coding System (HCPCS) Use and Maintenance of CPT-4 in HCPCS Local Codes Use and Acceptance of HCPCS Codes and Modifiers Deleted HCPCS Codes/Modifiers Payment, Utilization Review (UR), and Coverage Information on CMS Quarterly HCPCS Codes Update File Physician Fee Schedule Payment Policy Indicator File Record Layout
10321	Inpatient Rehabilitation Facility (IRF) Annual Update: Prospective Payment System (PPS) Pricer Changes for FY 2021
10322	Claim Status Category and Claim Status Codes Update
10323	Annual Update for the Health Professional Shortage Area (HPSA) Bonus Payments
10324	Implement Operating Rules - Phase III Electronic Remittance Advice (ERA) Electronic Funds Transfer (EFT): Committee on Operating Rules for Information Exchange (CORE) 360 Uniform Use of Claim Adjustment Reason Codes (CARC), Remittance Advice Remark Codes (RARC) and Claim Adjustment Group Code (CAGC) Rule - Update from Council for Affordable Quality Healthcare (CAQH) CORE
10325	Combined Common Edits/Enhancements Modules (CCEM) Code Set Update

10326	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
10328	January 2021 Healthcare Common Procedure Coding System (HCPCS) Quarterly Update Reminder
10329	Annual Clotting Factor Furnishing Fee Update 2021
10330	Instructions for Retrieving the January 2021 Medicare Physician Fee Schedule Database (MPFSDB) Files Through the CMS Mainframe Telecommunications System
10331	October 2020 Update of the Hospital Outpatient Prospective Payment System (OPPS)
10332	October 2020 Integrated Outpatient Code Editor (I/OCE) Specifications Version 21.3
10334	October Quarterly Update for 2020 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule
10337	National Coverage Determination (NCD30.3.3): Acupuncture for Chronic Low Back Pain (cLBP)
10338	Update to Hospice Payment Rates, Hospice Cap, Hospice Wage Index and Hospice Pricer for FY 2021
10339	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10341	Internet Only Manual Update to Pub. 100-04, Chapter 16, Section 60.1.2 and Pub. 100-04, Chapter 26, Section 10.4, Item 19 Independent Laboratory Specimen Drawing Items 14-33 - Provider of Service or Supplier Information and 40.2.4.
10343	Update to the Internet Only Manual (IOM) Publication (Pub.) 100-04, Chapter 32, Section 40.2.1 and 40.2.4.
10344	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
10348	October 2020 Update of the Ambulatory Surgical Center (ASC) Payment System
10350	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10354	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10356	Update to the Medicare Claims Processing Manual Site of Service Payment Differential MPFSDB File Record Layout and Field Descriptions
10357	Update to the Internet Only Manual (IOM) Publication (Pub.) 100-04, Chapter 9, Section 70.7 and 70.8.
10358	Instructions for Downloading the Medicare ZIP Code File for January 2021
10360	Fiscal Year (FY) 2021 Inpatient Prospective Payment System (IPPS) and Long Term Care Hospital (LTCH) PPS Changes
10371	Change to the Payment of Allogeneic
10373	October 2020 Update of the Hospital Outpatient Prospective Payment System (OPPS)

Medicare Secondary Payer (CMS-Pub. 100-05)	
10342	Update to the Model Admission Questions for Providers to Ask Medicare Beneficiaries Model Admission Questions to Ask Medicare Beneficiaries Documentation to Support the Admission Process
10359	Update to the Model Admission Questions for Providers to Ask Medicare Beneficiaries Model Admission Questions to Ask Medicare Beneficiaries Documentation to Support the Admission Process
Medicare Financial Management (CMS-Pub. 100-06)	
10203	The Fiscal Intermediary Shared System (FISS) Submission of Copybook Files to the Provider and Statistical Reimbursement (PS&R) System
10220	Notice of New Interest Rate for Medicare Overpayments and Underpayments -4th Qtr Notification for FY 2020
10226	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
10319	Removal of Contractor Requirement to Submit Electronic Data Interchange (EDI) Data into the Contractor Reporting of Operational and Workload Data (CROWD) System (Form 5)
Medicare State Operations Manual (CMS-Pub. 100-07)	
	None
Medicare Program Integrity (CMS-Pub. 100-08)	
10209	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10219	Moving Chapter 15 (Medicare Enrollment) Manual Instructions in Publication (Pub.) 100-08 to Chapter 10 (Medicare Enrollment) Introduction to Medicare Provider Enrollment Definitions Provider and Supplier Types/Services Certified Providers and Certified Suppliers That Enroll Via the Form CMS-855A Suppliers That Enroll Via the Form CMS-855B Individual Practitioners That Enroll Via the Form CMS-855I Other Medicare Part B Services Suppliers That Enroll Via the Form CMS-855S Medicare Diabetes Prevention Program (MDPP) Suppliers/Providers/Suppliers Not Eligible to Participate
10226	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10227	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10228	Updates to Chapters 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, and Exhibits of Publication (Pub.) 100-08
10234	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10235	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10345	Chapter 15 of Publication (Pub.) 100-08 Manual Redesign – Additional Release of Chapter 10

10347	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10353	Chapter 15 of Publication (Pub.) 100-08 Manual Redesign – Additional Release of Chapter 10 of Pub. 100-08, Modification of the Timeliness Standards
10355	Completion of Removal/Moving of Instructions from Chapter 15 of Publication (Pub.) 100-08 to Chapter 10 of Pub. 100-08 Certified Providers and Suppliers That Enroll Via the Form CMS-855 Suppliers that Enroll Via the Form CMS-855B Individual Practitioners that Enroll Via the Form CMS-855I Other Medicare Part B Services Suppliers That Enroll Via the CMS-855S Medicare Enrollment: Contractor Processing Duties Appeals Process Other Medicare Contractor Duties Application Return, Rejection, and Denial Letters Denial Model Letters Revocation Letters Corrective Action Plan (CAP) Model Letters Reconsideration Request Model Letters Deactivation Model Letters Rebuttal Model Letters Revalidation Notification Letters Model Identity Theft Prevention Letter Model Documentation Request Letter Medicare Program Integrity Manual Chapter 15 – Reserved for Future Use
Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)	
10303	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
Medicare Quality Improvement Organization (CMS- Pub. 100-10)	
	None
Medicare End Stage Renal Disease Network Organizations (CMS Pub 100-14)	
	None
Medicaid Program Integrity Disease Network Organizations (CMS Pub 100-15)	
	None
Medicare Managed Care (CMS-Pub. 100-16)	
	None
Medicare Business Partners Systems Security (CMS-Pub. 100-17)	
	None
Medicare Prescription Drug Benefit (CMS-Pub. 100-18)	
	None
Demonstrations (CMS-Pub. 100-19)	
10206	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10208	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10260	Implementation of Nurse Practitioners Certifying Diabetic Shoe Orders Under the Primary Care First (PCF) Model

10281	Primary Care First (PCF) and Serious Illness Patient (SIP) Models: Part 2: FFS Payments and other claims-based adjustments
10282	Telehealth Expansion Benefit Enhancement under the Pennsylvania Rural Health Model (PARHM) – Implementation
10289	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10294	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10307	The Intravenous Immune Globulin (IVIG) Demonstration: Demonstration is ending on December 31, 2020
10327	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10336	Implementation of Nurse Practitioners Certifying Diabetic Shoe Orders Under the Primary Care First (PCF) Model
10351	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
One Time Notification (CMS-Pub. 100-20)	
10205	New Point of Origin Code for Transfer from a Designated Disaster Alternate Care Site
10212	Reprocessing of Fiscal Year (FY) 2019 and 2020 Inpatient Prospective Payment System (IPPS) Claims for Certain Hospitals
10223	Medicare Appeals System (MAS) Enhanced Web Services for Part A Medicare Administrative Contractors.
10231	Addition of the QW modifier to Healthcare Common Procedure Coding System (HCPCS) code 87426
10240	IDR Shared Systems (IDRSS) Reference File Request for the Fiscal Intermediary Shared System (FISS) Adjustment Reason Codes
10241	Reason Code Updates for the 2020 Annual Therapy Current Procedural Terminology (CPT) Codes in Change Request (CR) 11501
10245	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10248	Health Insurance Portability and Accountability Act (HIPAA) Electronic Data Interchange (EDI) Front End Updates for January 2021
10250	Update the Combined Common Edits Module (CCEM) for Compatibility with JAVA Software Version 1.8 (also known as JAVA 8)
10252	COBOL Version 6.2 Upgrade - Phased Implementation for Fiscal Intermediary Shared System (FISS) and Multi Carrier System (MCS)
10258	Send Electronic Funds Transfer (EFT) Information from Provider Enrollment Chain and Ownership System (PECOS) to Multi-Carrier
10261	International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs)--January 2021 Update
10271	Utility to Reprocess Bypassed Common Working File (CWF) Informational Unsolicited Responses (IURs)
10275	Correction to Editing Update for Vaccine Services
10278	Create a New Media Preference Indicator Custom Format and New eMedicare Correspondence Preference Indicator
10283	COBOL Version 6.2 Upgrade - Phased Implementation for ViPS Medicare System (VMS) and the Common Working File (CWF)

10286	User CR: ViPS Medicare System (VMS) - Create a Beneficiary Record Submitted with Medicare Beneficiary Identifier (MBI) Waiver Claims
10287	CR: ViPS Medicare System (VMS) - Enhancements to the Claim Edit Audit Trail Screen (BUDS05)
10291	Expand Retention of Claims History for Outpatient, Part B, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) to 5 Years
10295	Shared System Support Hours for Application Programming Interfaces (APIs)
10300	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10301	Updates to Bills Pending Reports to Assist Medicare Administrative Contractors (MACs) with Monthly Status Report (MSR)
10302	Shared System Enhancement 2018: Rewrite Fiscal Intermediary Shared System (FISS) module FSSB6001, Common Working File (CWF) Unsolicited Response Function
10315	Updates to Nursing and Allied Health Education Medicare Advantage Payment Policies
10316	Revision to the Cost Report Acceptability Checklists - This CR Rescinds and Fully Replaces CR 10920.
10317	Update to the International Classification of Diseases, Tenth Revision (ICD-10) Diagnosis Codes for Vaping Related Disorder and Diagnosis and Procedure Codes for the 2019 Novel Coronavirus (COVID-19)
10333	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10352	Updates to Bills Pending Reports to Assist Medicare Administrative Contractors (MACs) with Monthly Status Report (MSR)
10361	Update to the Implementation of the Increased Payments for COVID-19 Discharges Under the Inpatient Prospective Payment System (IPPS) Under Section 3710 of the CARES Act
Medicare Quality Reporting Incentive Programs (CMS- Pub. 100-22)	
10340	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
State Payment of Medicare Premiums (CMS-Pub.100-24)	
4	New State Payment of Medicare Premiums, (SPMP)
Information Security Acceptable Risk Safeguards (CMS-Pub. 100-25)	
10362	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction

Addendum II: Regulation Documents Published in the Federal Register (July through September 2020)

Regulations and Notices

Regulations and notices are published in the daily **Federal Register**. To purchase individual copies or subscribe to the **Federal Register**, contact GPO at www.gpo.gov/fdsys. When ordering individual

copies, it is necessary to cite either the date of publication or the volume number and page number.

The **Federal Register** is available as an online database through GPO Access. The online database is updated by 6 a.m. each day the **Federal Register** is published. The database includes both text and graphics from Volume 59, Number 1 (January 2, 1994) through the present date and can be accessed at <http://www.gpoaccess.gov/fr/index.html>. The following website <http://www.archives.gov/federal-register/> provides information on how to access electronic editions, printed editions, and reference copies.

This information is available on our website at: <https://www.cms.gov/files/document/regs3q20qpu.pdf>

For questions or additional information, contact Terri Plumb (410-786-4481).

Addendum III: CMS Rulings (July through September 2020)

CMS Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, private health insurance, and related matters.

The rulings can be accessed at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings>. For questions or additional information, contact Tiffany Lafferty (410-786-7548).

Addendum IV: Medicare National Coverage Determinations (July through September 2020)

Addendum IV includes completed national coverage determinations (NCDs), or reconsiderations of completed NCDs, from the quarter covered by this notice. Completed decisions are identified by the section of the NCD Manual (NCDM) in which the decision appears, the title, the date the publication was issued, and the effective date of the decision. An NCD is a determination by the Secretary for whether or not a particular item or service is covered nationally under the Medicare Program (title XVIII of the Act), but does not include a determination of the code, if any, that is assigned to a particular covered item or service, or payment determination for a particular covered item or service. The entries below include information concerning completed decisions, as well as sections on

program and decision memoranda, which also announce decisions or, in some cases, explain why it was not appropriate to issue an NCD. Information on completed decisions as well as pending decisions has also been posted on the CMS website. For the purposes of this quarterly notice, we are providing only the specific updates to national coverage determinations (NCDs), or reconsiderations of completed NCDs published in the 3-month period. This information is available at: www.cms.gov/medicare-coverage-database/. For questions or additional information, contact Wanda Belle, MPA (410-786-7491).

Title	NCDM Section	Transmittal Number	Issue Date	Effective Date
Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer	NCD 90.2	10346	09/11/2020	01/28/2020

Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (July through September 2020)
(Inclusion of this addenda is under discussion internally.)

Addendum VI: Approval Numbers for Collections of Information (July through September 2020)

All approval numbers are available to the public at Reginfo.gov. Under the review process, approved information collection requests are assigned OMB control numbers. A single control number may apply to several related information collections. This information is available at www.reginfo.gov/public/do/PRAMain. For questions or additional information, contact William Parham (410-786-4669).

Addendum VII: Medicare-Approved Carotid Stent Facilities (July through September 2020)

Addendum VII includes listings of Medicare-approved carotid stent facilities. All facilities listed meet CMS standards for performing carotid artery stenting for high risk patients. On March 17, 2005, we issued our decision memorandum on carotid artery stenting. We determined that carotid artery stenting with embolic protection is reasonable and necessary only if performed in facilities that have been determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes. We have created a list of minimum standards for facilities modeled in part on professional society statements on competency.

All facilities must at least meet our standards in order to receive coverage for carotid artery stenting for high risk patients. For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available at: <http://www.cms.gov/MedicareApprovedFacilities/CASF/list.asp#TopOfPage>. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Facility	Provider Number	Effective Date	State
The following facilities are new listings for this quarter.			
Arnot Ogden Medical Center 600 Roe Avenue Elmira, NY 14905	330090	07/14/2020	NY
McLeod Loris Seacoast Hospital 14000 Highway 9 East Little River, SC 29566	420105	08/11/2020	SC
<u>Other Information:</u> dba McLeod Health Seacoast			
Orlando Health – South Seminole Hospital 555 State Road 434 Longwood, FL 32750	1184709057	09/22/2020	FL
The following facilities have editorial changes (in bold).			
FROM: Ingham Regional Medical Center TO: McLaren Greater Lansing 401 West Greenlawn Avenue Lansing, MI 48910	230167	09/22/2005	MI
FROM: St Mary's of Michigan TO: Ascension St Mary's Hospital 800 S. Washington Avenue Saginaw, MI 48601	230077	01/12/2006	MI

**Addendum VIII:
American College of Cardiology's National Cardiovascular Data Registry Sites (July through September 2020)**

The initial data collection requirement through the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) has served to develop and improve the evidence base for the use of ICDs in certain Medicare beneficiaries. The data collection requirement ended with the posting of the final decision memo for Implantable Cardioverter Defibrillators on February 15, 2018.

For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum IX: Active CMS Coverage-Related Guidance Documents (July through September 2020)

CMS issued a guidance document on November 20, 2014 titled “Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development Document”. Although CMS has several policy vehicles relating to evidence development activities including the investigational device exemption (IDE), the clinical trial policy, national coverage determinations and local coverage determinations, this guidance document is principally intended to help the public understand CMS’s implementation of coverage with evidence development (CED) through the national coverage determination process. The document is available at <http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27>. There are no additional Active CMS Coverage-Related Guidance Documents for the 3-month period. For questions or additional information, contact JoAnna Baldwin, MS (410-786-7205).

Addendum X:

List of Special One-Time Notices Regarding National Coverage Provisions (July through September 2020)

There were no special one-time notices regarding national coverage provisions published in the 3-month period. This information is available at <http://www.cms.gov>. For questions or additional information, contact JoAnna Baldwin, MS (410-786 7205).

Addendum XI: National Oncologic PET Registry (NOPR) (July through September 2020)

Addendum XI includes a listing of National Oncologic Positron Emission Tomography Registry (NOPR) sites. We cover positron emission tomography (PET) scans for particular oncologic indications when they are performed in a facility that participates in the NOPR.

In January 2005, we issued our decision memorandum on **positron emission tomography** (PET) scans, which stated that CMS would cover PET scans for particular oncologic indications, as long as they were performed in the context of a clinical study. We have since recognized the National Oncologic PET Registry as one of these clinical studies.

Therefore, in order for a beneficiary to receive a Medicare-covered PET scan, the beneficiary must receive the scan in a facility that participates in the registry. There were no additions, deletions, or editorial changes to the listing of National Oncologic Positron Emission Tomography Registry (NOPR) in the 3-month period. This information is available at <http://www.cms.gov/MedicareApprovedFacilitie/NOPR/list.asp#TopOfPage>. For questions or additional information, contact David Dolan, MBA (410-786-3365).

Addendum XII: Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities (July through September 2020)

Addendum XII includes a listing of Medicare-approved facilities that receive coverage for ventricular assist devices (VADs) used as destination therapy. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy. On October 1, 2003, we issued our decision memorandum on VADs for the clinical indication of destination therapy. We determined that VADs used as destination therapy are reasonable and necessary only if performed in facilities that have been determined to have the experience and infrastructure to ensure optimal patient outcomes. We established facility standards and an application process. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy.

For the purposes of this quarterly notice, we are providing only the specific updates to the list of Medicare-approved facilities that meet our standards that have occurred in the 3-month period. This information is available at <http://www.cms.gov/MedicareApprovedFacilitie/VAD/list.asp#TopOfPage>. For questions or additional information, contact David Dolan, MBA, (410-786-3365).

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
The following facilities are new listings for this quarter.				
University Health Services, Inc d/b/a University Hospital 1350 Walton Way Augusta, GA 30901	110028	08/28/2020		GA
<u>Other information:</u> Joint Commission ID # 564723-2020-VAD				

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
St. Elizabeth Healthcare 1 Medical Village Drive Edgewood, KY 41017 <u>Other information:</u> Joint Commission ID # 188468-2020-VAD	180035	08/12/2020		KY
AMITA Health Alexian Brothers Medical Center 800 Biesterfield Rd Elk Grove Village, IL 60007 <u>Other information:</u> DNV GL ID # 185936-2020-VAD	140258	07/21/2020		IL
Heart Hospital of Austin, A campus of St. David's Medical Center 3801 N. Lamar Blvd Austin, TX 78756 <u>Other information:</u> DNV GL ID # 181413-2020- VAD	450431	07/27/2020		TX
The following facilities have editorial changes (in bold).				
NYU Langone Hospitals 550 First Avenue New York, NY 10016 <u>Other information:</u> Joint Commission ID # 5820 Previous Re-certification Dates: 02/14/2012; 01/14/2014; 03/08/2016; 03/27/2018	330214	02/14/2012	08/26/2020	NY
University of Kentucky Hospital 800 Rose Street Lexington, KY 40536-0293 <u>Other information:</u> Joint Commission ID # 7760 Previous Re-certification Dates: 02/10/2009; 09/20/2011; 09/18/2013; 11/03/2015; 12/05/2017	180067	02/10/2009	02/26/2020	KY

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
Sutter Medical Center 2825 Capitol Ave Sacramento, CA 95816 <u>Other information:</u> Joint Commission ID # 2902 Previous Re-certification Dates: 10/20/2009; 09/22/2011; 10/17/2013; 10/27/2015; 11/07/2017	050108	10/20/2009	03/04/2020	CA

Addendum XIII: Lung Volume Reduction Surgery (LVRS) (July through September 2020)

Addendum XIII includes a listing of Medicare-approved facilities that are eligible to receive coverage for lung volume reduction surgery. Until May 17, 2007, facilities that participated in the National Emphysema Treatment Trial were also eligible to receive coverage. The following three types of facilities are eligible for reimbursement for Lung Volume Reduction Surgery (LVRS):

- National Emphysema Treatment Trial (NETT) approved (Beginning 05/07/2007, these will no longer automatically qualify and can qualify only with the other programs);
- Credentialed by the Joint Commission (formerly, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)) under their Disease Specific Certification Program for LVRS; and
- Medicare approved for lung transplants.

Only the first two types are in the list. There were no updates to the listing of facilities for lung volume reduction surgery published in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilities/LVRS/list.asp#TopOfPage. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (July through September 2020)

Addendum XIV includes a listing of Medicare-approved facilities that meet minimum standards for facilities modeled in part on professional society statements on competency. All facilities must meet our standards in order to receive coverage for bariatric surgery procedures. On February 21, 2006, we issued our decision memorandum on bariatric surgery procedures.

We determined that bariatric surgical procedures are reasonable and necessary for Medicare beneficiaries who have a body-mass index (BMI) greater than or equal to 35, have at least one co-morbidity related to obesity and have been previously unsuccessful with medical treatment for obesity. This decision also stipulated that covered bariatric surgery procedures are reasonable and necessary only when performed at facilities that are: (1) certified by the American College of Surgeons (ACS) as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery (ASBS) as a Bariatric Surgery Center of Excellence (BSCOE) (program standards and requirements in effect on February 15, 2006).

There were no additions, deletions, or editorial changes to Medicare-approved facilities that meet CMS' minimum facility standards for bariatric surgery that have been certified by ACS and/or ASMBS in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilities/BSF/list.asp#TopOfPage. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (July through September 2020)

There were no FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the 3-month period.

This information is available on our website at www.cms.gov/MedicareApprovedFacilities/PETDT/list.asp#TopOfPage. For questions or additional information, contact David Dolan, MBA (410-786-3365).

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